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UNCLAS SECTION 01 OF 02 OTTAWA 002021

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STATE PASS TO USTR FOR GARDE, ESPINEL, CHANDLER
STATE PASS TO USDOC FOR GWORD, JBOGER
STATE PASS TO USPTO FOR MKEPLINGER

E.O. 12958: N/A
TAGS: KIPR ECON TBIO CA
SUBJECT: POTENTIAL FOR IPR PROGRESS: CANADA'S PROPOSED DATA PROTECTION REGULATIONS

REF: A. OTTAWA 1701

¶B. OTTAWA 1317

¶1. (SBU) Summary: The GOC has proposed a two-regulation package (significantly different from its 2004 proposal) consisting of data protection for the innovative pharmaceutical industries and "Patented Medicines (Notice of Compliance)" for the generic drug industries, a combination designed to force compromise between the two sectors. Although the innovative pharmaceutical industry organizations PhRMA and Rx&D have minor complaints which they hope to have addressed in the final regulations (the comment period ends July 17), in general the package seems to be a positive development for IPR protection in Canada. In particular, the Data Protection regulation is designed to bring Canada into compliance with its international obligations to provide protection for proprietary data belonging to patent-holding companies, something that the Embassy has been encouraging. Assuming the proposed rules are finalized, industry observes believe that this will be a step forward for Canada's protection of IPR and will directly address one complaint from the last two Special 301 Reports on Canada. End Summary.

The Regulations

¶2. (U) (SBU) The Patented Medicines (Notice of Compliance) or PMNOC regulation and, to a lesser extent, the Data Protection regulation are complex, and we would welcome insights from USG experts. The data protection regulation can be found at
canadagazette.gc.ca/partI/2006/20060617/html/ regle4-e.html
The PMNOC regulation can be found at
canadagazette.gc.ca/partI/2006/20060617/html/ regle6-e.html
Our initial perusal and conversations with contacts have provided the following information.

¶3. (SBU) The draft Data Protection regulation stipulates that a secondary manufacturer (usually a generic) cannot file a new drug submission on the basis of a direct or indirect comparison between the new drug and an innovative drug until six years after the first notice of compliance was issued to the innovator. The submission will not be approved until at least eight years after the first notice of compliance was issued. This data protection period of eight years compares favorably to the U.S. "five plus three" period. (Comment: One observer joked to us that now Canada would have better data protection than the United States and that the innovative industry may start to use this as leverage to argue for better data protection in the United States. End comment.) Both the Canadian industry group Rx&D and PhRMA in

the United States are preparing comments to submit to Health Canada. From discussions with industry contacts, we believe the industry comments will focus on requests for clarification, particularly surrounding the transitional language that will determine how drug submissions already in the pipeline are treated. A particular point which seems unclear to many observers (and of concern to the pharmaceutical industry) is paragraph (5) which states that the eight year protection period does not apply "if the innovative drug is not being marketed in Canada." We expect that the final regulations will clarify how this will be applied. However, the innovative industry's reaction to the data protection regulation is positive, with observers stating that this will not only bring Canada into compliance with its international obligations but will also make the country more competitive internationally.
Qcountry more competitive internationally.

¶4. (SBU) The Patented Medicines (Notice of Compliance) or PMNOC regulation is the part of the package designed to keep the generic companies in the deal. The PMNOC regulation is more complex than the data protection regulation, but in general it is intended to limit innovative drug companies' ability to "evergreen" drug patents, or renew patents based on small changes to a drug. The PMNOC regulation attempts to address the unintended consequences of unclear language in previous regulation which required court interpretation; these include the "possibility that an innovator company may delay generic market entry by listing new and sometimes irrelevant patents on the basis of minor product revisions." In what seems to be a valuable victory for the innovative drug industry, however, the PMNOC's Regulatory Impact Assessment Statement states that dosage form patents (patents that focus on the form of the drug, not its chemical composition) deserve "special protection provided by the PM(NOC) regulations," adding that this is "particularly true

in the case of biologic drugs where effective administration of the medicinal ingredient is often dependent on the development of new and innovative delivery mechanisms." The generic industry in Canada has not made any public statement on the draft regulations, although they will probably submit formal comments. Our contacts also tell us that the generics are trying to arrange for meetings with relevant officials and members of parliament before the comment period ends on July 17.

GOC Officials' Perspective

¶5. (SBU) Our GOC contacts seem confident that these regulations will be finalized, with very few changes, in as short a period as is possible under Canada's regulatory process. They describe the regulations as fair and balanced, and they suggest that neither the innovative nor the generic industry should be surprised by the regulations' content. In general, this is what we are hearing from industry contacts as well, although industry contacts hesitate to describe themselves as happy with the regulations and insist that certain changes need to be made. Any rhetoric about pushing for 10 years of data protection such as in Europe seems to be more a bargaining tool than an actual goal. GOC officials are aware that both industries, but particularly the innovative industry, are eager for a package to be finalized and are willing to accept the compromises inherent in these proposed regulations.

Domestic Political Context

¶6. (SBU) The current Conservative government has been more receptive to U.S. concerns about intellectual property rights, and domestically the Conservative party is less beholden to the generic industry, which is predominantly based in the greater Toronto area, a Liberal stronghold.

(Comment: a recent bit of much-hyped campaign scandal involved questionable donations to a Toronto-area Liberal MP--totalling C$54,000--from Apotex Inc's top two executives, their wives and six children. Apotex is Canada's largest generic drug company. End comment.) The innovative drug companies, on the other hand, are primarily based in Quebec, where the Conservatives are very interested in picking up additional seats. In general, this suggests that the generics industry, which is thought to be responsible for delaying progress on the 2004 proposal of the first version of these regulations, will not be able to delay progress on the new draft regulations. The most optimistic timeframe for final regulations is probably the end of 2006. As with our other IPR goal of amendments to the copyright act, much will hinge on whether another election is called in the meantime. An election before finalization of the regulations would at the very least delay them regulations and could result in yet another redraft.

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